

**LABEL, IN PART:** (Bottle) "Caution—To Be Used Only By Or On The Prescription Of A Physician 25 Tasapan Pearls \* \* \* A carefully prepared combination of pennyroyal, apiol, powdered ext. of ergot, aloin, savin, rue, and vegetable oil in a soft gelatin pearl."

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to reveal the purposes for which the article was to be taken; and, Section 503 (b) (4), the article was a drug which was subject to Section 503 (b) (1) (B), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription." The article was misbranded while held for sale after shipment in interstate commerce.

**DISPOSITION:** March 24, 1954. Default decree of condemnation and destruction.

**DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS\***

**4349. Misbranding of pituitary tablets. U. S. v. 1 Bottle \* \* \*. (F. D. C. No. 36288. Sample No. 82555-L.)**

**LIBEL FILED:** January 14, 1954, Western District of New York.

**ALLEGED SHIPMENT:** On or about August 24, 1953, by Richlyn Laboratories, from Philadelphia, Pa.

**PRODUCT:** 1 bottle containing 10,000 *pituitary tablets* at Rochester, N. Y.

**NATURE OF CHARGE:** Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it did not state the conditions in which the article was to be used.

**DISPOSITION:** February 12, 1954. Default decree of condemnation and destruction.

**4350. Misbranding of Triulcin tablets. U. S. v. 13 Cases, etc. (F. D. C. No. 36072. Sample No. 50541-L.)**

**LIBEL FILED:** November 4, 1953, Southern District of New York.

**ALLEGED SHIPMENT:** On or about September 10, 1953, from Newark, N. J.

**PRODUCT:** *Triulcin tablets*. 13 cases, containing a total of 86,600 tablets, and 126 cartons, each carton containing 100 tablets and a leaflet entitled "Further Facts About Triulcin," at New Rochelle, N. Y., in possession of S. B. Leonardi & Co., Inc., together with an additional quantity of the leaflets and a number of empty cartons labeled in the same manner as the 126-carton lot.

**RESULTS OF INVESTIGATION:** When originally shipped from Newark, N. J., the tablets were contained in 15 cases, each containing 140 cellophane strips and each strip containing 50 tablets. Upon receipt of the tablets by the consignee, a portion of the shipment was repackaged into cartons, with the balance of the shipment, consisting of 13 cases, being held for repackaging into the above-mentioned empty cartons.

**LABEL, IN PART:** (Carton) "Triulcin Indicated for relief of stomach Ulcer Pains and discomfort due to excessive stomach acidity 100 Tablets \* \* \*

**Active Ingredients:** Hibiscus Esculentus, Water-soluble Chlorophyllin, Aluminum Hydroxide Gel, Magnesium Trisilicate, Excipients and Flavor. Average Dose: 10 tablets daily—2 on arising, 2 on retiring, and 2 after each meal (at

\*See also No. 4348.

least one hour after the meal). Take with minimum amount of water. More rapidly effective when chewed before swallowing."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements on the carton label and on the above-mentioned leaflet accompanying the article contained in the cases and in the cartons were false and misleading. The statements represented and suggested that the article in the cases and cartons was an adequate and effective treatment for gastric and duodenal ulcers and would completely heal ulcer craters.

Further misbranding, Section 502 (f) (1), the labeling of the repackaged article contained in the cartons failed to bear adequate directions for use since the directions on the carton "Average Dose: 10 tablets daily—2 on arising, 2 on retiring, and 2 after each meal (at least one hour after the meal). Take with minimum amount of water. More rapidly effective when chewed before swallowing" were not adequate directions for use in the treatment of gastric and duodenal ulcers.

The article contained in the cases and as repackaged in the cartons was misbranded while held for sale after shipment in interstate commerce.

**DISPOSITION:** May 26, 1954. Torbert Laboratories, Inc., New Rochelle, N. Y., claimaint, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for the destruction of the labeled cartons and leaflets and the relabeling of the product under the supervision of the Food and Drug Administration.

#### **DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS**

4351. Adulteration of oxygen. U. S. v. John Suydam (Newburgh Oxygen Co.), and George H. Gordon. Pleas of guilty. Fine of \$750 against Defendant Suydam and \$150 against Defendant Gordon. Jail sentence of 6 months against Defendant Suydam suspended and defendant placed on probation for 6 months; jail sentence of 3 months against Defendant Gordon also suspended and this defendant placed on probation for 3 months. (F. D. C. No. 30044. Sample Nos. 73341-K, 73343-K, 74527-K.)

**INFORMATION FILED:** February 7, 1952, Southern District of New York, against John Suydam, trading as the Newburgh Oxygen Co., Newburgh, N. Y., and George H. Gordon, an employee in the business.

**ALLEGED VIOLATION:** At a time prior to April 25, 1950, while a large metal cylinder of carbon dioxide was being held for sale at the Newburgh Oxygen Co., after shipment in interstate commerce, the defendants repacked a quantity of the carbon dioxide into a small metal cylinder and attached to the cylinder a tag containing the printed and graphic matter set forth below; and, on or about April 25, 1950, the defendants sold and delivered the small metal cylinder containing carbon dioxide, and in the invoice of such sale, represented that this metal cylinder contained *oxygen*. It was alleged that such acts of repacking and labeling of the article in the small metal cylinder resulted in the article in the small cylinder being adulterated.

**LABEL, IN PART:** (Tag) "Newburgh Oxygen Co. Newburgh, N. Y. Phone 2745 Carbon Dioxide—% Oxygen Only—% Cyl. No.— Filled 4/25/50 Empty —Tear Off here when empty Full."

**NATURE OF CHARGE:** Adulteration, Section 501 (d) (2), carbon dioxide had been substituted for *oxygen*, which the article was represented to be.